DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Mini Lap Technologies, Inc.
% Mr. Joseph Azary
Azary Technologies, LLC
543 Long Hill Avenue
Shelton, CT 06484

JUL 27 2015

Re: K070686
Trade/Device Name: MINI LAP Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated (Date on orig SE ltr): March 5, 2007
Received (Date on orig SE ltr): March 13, 2007

Dear Mr. Azary,

This letter corrects our substantially equivalent letter of April 5, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: MINI LAP Instruments

Indications For Use: K070686

The MINI LAP Instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold, and manipulate other soft internal tissues as well as items such as hernia mesh.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070686

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APR 5 - 2007

510 (k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

March 5, 2007

Submitter's Information [21 CFR 807.92(a)(1)]

Regulatory Contact
Joseph Azary
Azary Technologies LLC
543 Long Hill Avenue
Shelton, CT 06484
Tel: (203) 944-9320
Fax: (203) 944-9317
Email: info@azarytech.com

Sponsor / Manufacturer
Mini Lap Technologies Inc.
88 Ashford Avenue
Dobbs Ferry, NY 10522

Tel: 914 591 8400

FDA Establishment Registration is pending.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name

- MINI LAP Instruments

Device Common, Usual, or Classification Names

- Grasping Instruments, Laparoscopic Instruments, Graspers, Cannula, Trocar, Manual Surgical Instruments

Classification Panel

- Classification of this device would fall under the responsibility of the Gastroenterology / Urology panel.

Class

Based on our research as well as the 513(g) letter from FDA we believe the device is a class 2 device classified under the following Product Codes:

- KOG, 21 CFR 876.1500, Endoscope Accessories
- HET, 21 CFR 884.1720, Gynecological Laparoscope Accessories
- KOA, 21 CFR 876.4730 Manual Surgical Instruments
- FBQ, 21 CFR 878.5090 Trocar

Predicate Device [21 CFR 807.92(a)(3)]

- U.S. Surgical Corp – MiniSite 2mm Laparoscopic Instruments – K951173
- U.S. Surgical Corp – MiniPort 2mm - K062326*
- U.S. Surgical Corp – Versaport trocar with fixation sleeve – K062326
- Taut – Adapt Pediatric Access Ports K012007 / K992904

Description of the Device [21 CFR 807.92(a)(4)]

The MINI LAP Instruments are a family of minimally invasive devices. The devices penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold, and manipulate other soft internal tissues as well as items such as hernia mesh.

Prior to insertion, the physician must depress the safety button and retract the instrument into the needle. The needle is inserted through the soft tissue under visualization. Once the needle has penetrated the soft tissue, the physician will advance the instrument into the body cavity using the handle. As the instrument advances, the jaws of the instrument will open. The instrument will be offered in various configurations including babcock clamp, bowel clamp, and hernia clamp. The device includes a self-activating safety that prohibits the jaws from returning to their fully retracted position while in use, which acts as a blunt shield for the sharp needle tip.

The device is provided in the following configurations:

Length	Clamp Type
150mm	Bowel Clamp
150mm	Babcock Clamp
150mm	Hernia Clamp
200mm	Bowel Clamp
200mm	Clinch Clamp
200mm	Babcock Clamp
200mm	Gallbladder Clamp
250mm	Bowel Clamp
250mm	Gallbladder Clamp
250mm	Babcock Clamp
250mm	Clinch Clamp

The devices are sterile disposable, single patient only. The devices were designed to hold pneumoperitoneum during use..

Intended Use [21 CFR 807.92(a)(5)]

The MINI LAP Instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold, and manipulate other soft internal tissues as well as items such as hernia mesh.

Technological Characteristics [21 CFR 807.92(a)(6)]

We believe the MINI LAP instruments are substantially equivalent to the predicate devices.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed a variety of mechanical tests and evaluations. Additionally, the device is composed of biocompatible materials with a history of usage in the medical device industry.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.